

## **REMARKS**

The Office Action and communications mailed April 16, September 4, and October 2, 2007 have been reviewed, and the comments of the U.S. Patent Office have been considered. Claims 1-11, 14-24, and 27-32 are pending in this application. By this Amendment, claims 1, 18, 21, and 23 have been amended, and claims 27-32 have been added. The amendments are supported in the specification by at least paragraphs [0031]-[0033], and by Figs. 4-13.

The rejection of claim 4 under 35 U.S.C. §112, second paragraph, set forth in the April 16, 2007 Office Action has been withdrawn by the September 4 Advisory Action.

The Office objects to the drawings because the drawings purportedly do not show all of the features recited in claims 7 and 8. The Office Action at page 5 also states that "a vascular prosthesis having two ends of generally similar geometries ... is not conveyed to the ordinary practitioner by the drawings." Applicants respectfully traverse the objection and traverse the Office's assertion because a person of ordinary skill would be able to understand the claimed invention from the as-filed drawings.

The as-filed drawings already convey a two-end prosthesis to a person of ordinary skill. Specifically, Figs. 4-18 illustrate an end of tube 52 with a break line, which is a symbol having a universally recognized conventional meaning and generally accepted in the art to represent a continuation of tube 52. *See* 37 C.F.R. §1.84(n). The specification explains that the enlargement 54 illustrated in Figs. 4-8 (and Figs. 9-13) can be at one or both ends of tube 52, and the figures provide a representative enlargement 54 on a tube 52. *See* paragraph [0031] and Figs. 4-13 of the application. The continuation of tube 52 represented by the break line and the corresponding portions of the specification thus convey to a person of ordinary skill that the subject matter of claims 7 and 8 is illustrated in the figures. Furthermore, in the embodiment illustrated in Figs. 4-13, each end of the two-end prosthesis is identical to each other (and thus both ends of the two-end prosthesis are presently shown in a single figure), and a modification of the drawings to illustrate two identical ends is not necessary to assist a person of ordinary skill in understanding the invention.

Moreover, 35 U.S.C. §113 states that the "applicant shall furnish a drawing where necessary for the understanding of the subject matter to be patented" (emphasis added). 37 C.F.R. §1.81(a) likewise requires drawings "where necessary for the understanding of the subject

matter sought to be patented." Applicants respectfully submit that an additional drawing redisplaying the same structure already illustrated in Figs. 4-13 is not necessary for the understanding of the subject matter recited in claims 7-8, or in the other pending claims. Applicants further submit that a person of ordinary skill evaluating the application and current drawings would understand the subject matter to be patented, and the Office has not established how a person of ordinary skill would be unable to understand the claimed invention. It is respectfully requested that the objection be withdrawn.

Claims 1-5, 7-11, 14, 16, 18, 19, and 21 stand rejected under 35 U.S.C. §102(b) over Rayhanabad (U.S. Pat. No. 4712551); and claims 6, 15, 17, 20, and 22 stand rejected under 35 U.S.C. §103(a) over Rayhanabad. The rejections are respectfully traversed.

With regard to independent claims 1, 18, and 21, Rayhanabad fails to show or describe a vascular prosthesis with an end formation defining an enlarged chamber that terminates at an open end of the vascular prosthesis to define an opening, the opening having a non-circular perimeter outlining a cross-sectional area that is larger than a cross-sectional area of the tubular portion (or first diameter portion).

Rayhanabad shows and describes mouth 22 to have an elliptical cross section, and no other structure in Rayhanabad is shown or described to have a non-circular cross section. *See* Rayhanabad at col. 5 (lines 26-32) and Fig. 2. Rayhanabad further states that "the cross-sectional area of the inlet end 12 increases from the mouth 22 ... towards the distal end 16." *See* Rayhanabad at col. 5 (lines 33-36). Rayhanabad thus describes mouth 22 to have the smallest cross-sectional area of the inlet end 12 and, therefore, mouth 22 does not have a cross-sectional area that is larger than the remainder of inlet end 12. Rayhanabad also provides specific diameters for mouth 22 and the distal-most end of the inlet end 12 that shows mouth 22 to have a smaller cross-sectional area than the cross-sectional area of the inlet end 12. *See* Rayhanabad at col. 5 (lines 29-32 and 36-40).

The Office Action at pages 3 and 5 asserts that the claimed "non-circular open end perimeter" is found in Rayhanabad's shunt 10 at the outermost radial extent of balloon 32. Specifically, the Office asserts that the radially-outermost limits of balloon 32 "defines a non-circular open-end perimeter". Applicants respectfully traverse the Office's interpretation of Rayhanabad because the only structure in Rayhanabad shown or described to have an elliptical cross section is mouth 22, and there is no showing or description in Rayhanabad supporting the

Office's interpretation that the "outer limits" of balloon 32 are non-circular. The Office's interpretation of Rayhanabad thus fails to support a rejection under §102(b).

Claims 23-24 stand rejected under 35 U.S.C. §102(e) over Butters (U.S. Pat. No. 6019788). The rejection is respectfully traversed.

With regard to independent claim 23, Butters fails to show or describe vascular prosthesis comprising a continuous expanded polytetrafluoroethylene structure with a generally uniform inner surface, or an enlargement with the inner surface of the enlargement defining an enlarged chamber including a distal end defining an oval opening with a major diameter larger than an inner diameter of the tubular part.

Butters shows and describes a series of separate components joined together to form device 10. As shown in Fig. 3 of Butters, device 10 is made of a cuff 28 that is heat sealed to conduit 16. *See* Butters at col. 8, line 4. Accordingly, Butters fails to show or describe a continuous expanded polytetrafluoroethylene structure.

Furthermore, Butters also fails to show or describe vascular prosthesis with a structure with an enlargement with an inner surface of the enlargement defining an enlarged chamber. As shown in Butters at Figs. 8A-8E, the conduit 16 extends through cuff 28 and thus maintains a constant inner diameter along the length of device 10. Butters also describes cuff 28 to surround conduit 16, and thus does not form a part of the interior of conduit 16. *See* Butters at col. 7 (line 5). Butters thus fails to show or describe cuff 28 defining an enlarged chamber in the Butters device.

With regard to claim 24 and Butters, Applicants also traverse the Office's assertion regarding inherency. Specifically, the Office Action at page 4 asserts that "a reduced diameter of the tubular part 16 within cuff 28 would have been inherent from the sealing attachment of the cuff onto the tubular part ... and/or from the fact that the blood conduit 16 can be stepped". MPEP §2112(IV) states that:

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

The Office Action fails to establish inherency because the allegedly-inherent "reduced diameter" feature is not necessarily present in the Butters device 10. Butters states that the "cuff 28 may be provided on the conduit 16 to further improve the anchoring" of the conduit to a blood vessel (*see* Butters at col. 7 (lines 1-3)) and states that conduit 16 "may be provided in straight, tapered, stepped, or other forms" (*see* Butters at col. 7 (lines 43-44)). However, the mere fact that these features may possibly exist in the Butters device is not sufficient to establish inherency and, even if present, the features do not necessarily create a "reduced diameter". Furthermore, the portions of Butters cited by the Office do not establish that the allegedly-inherent "reduced diameter" feature is disposed on the Butters device 10 "adjacent" to an "enlargement" as recited in claim 24.

For the foregoing reasons, Rayhanabad and Butters each fail to show or describe all of the features recited in independent claims 1, 18, 21, and 23, and the dependent claims thereof. It is respectfully requested that the rejections be withdrawn.

New claims 27-32 are allowable for at least the same reasons provided above for independent claims 1, 18, 21, and 23.

## CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this Application and the prompt allowance of at least the pending claims.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,



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